NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRIAN F. DELANEY, Plaintiff, v. STRYKER ORTHOPAEDICS, formerly known as HOWMEDICA/OSTEONICS, a wholly owned subsidiary of STRYKER CORPORATION, ABC CORPORATIONS 1-10 (a fictitious name), JOHN DOES 1-10 (a fictitious name), individually, and as agents, servants, or employees of STRYKER CORPORATION and/or STRYKER ORTHOPAEDICS and/or HOWMEDICA/OSTEONICS, Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No.08-03210 (DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motion by Defendant Howmedica Osteonics Corp. ("HOC")[1] to dismiss Plaintiff Brian Delaney's ("Mr. Delaney") Complaint for failure to state a claim upon which relief can be granted pursuant to FED. R. CIV. P. 12(b)(6). Pursuant to FED. R. CIV. P. 78, no oral argument was heard. After carefully considering the submissions of the parties, and based upon the following, it is the finding of the Court that HOC's motion to dismiss is **granted** in part and **denied** in part.

[1] HOC is improperly named in the Complaint as Howmedica/Osteonics; and Stryker Orthopaedics is improperly named in the Complaint as the entity formerly known as Howmedica/Osteonics. Additionally, Plaintiff improperly served Stryker Corporation, HOC's parent corporation, at HOC's corporate offices rather than serving HOC.

I. BACKGROUND[2]

A. Factual Background

Mr. Delaney underwent total left hip arthroplasty surgery (hip replacement surgery) on March 29, 2005, at which time his hip was replaced with HOC's Trident™ hip prosthesis. Dr. Jonathan Hottenstein performed the surgery at the Sewickley Valley Hospital in Sewickley, Pennsylvania.

On May 28, 2006, the ceramic femoral ball component of Mr. Delaney's prosthesis shattered. The reason for the component failure is currently unknown. Dr. Hottesnstein replaced Mr. Delaney's prosthesis on May 29, 2006.

HOC's Trident™ hip prosthesis is a Class III medical device. The United States Food and Drug Administration ("FDA") first approved its use in the United States on February 3, 2003, after performing the statutory pre-market approval ("PMA") process established by the 1976 Medical Device Amendments ("MDA") of the Food, Drug and Cosmetic Act ("FDCA"). Mr. Delaney alleges that HOC has since changed certain design characteristics and the manufacturing process without formal FDA approval.

B. Procedural Background

Mr. Delaney commenced this products liability action in the Superior Court of New Jersey, Bergen County, Law Division on May 13, 2008. HOC removed the case to this Court on June 27, 2008. Thereafter, HOC requested and received an extension of time to respond to Mr. Delaney's Complaint. HOC filed this motion to dismiss on July 22, 2008.

Mr. Delaney alleges causes of action for violation of federal law and regulations, namely the FDCA. Mr. Delaney asserts eight Counts: 1) failure to warn; 2) defective manufacture; 3) defective

[2] The facts set forth in this Opinion are taken from the parties' respective papers.

design; 4) negligence and recklessness; 5) breach of express and implied warranties; 6) breach of implied warranty of fitness; 7) breach of implied warranty of merchantability; and 8) consumer fraud pursuant to the New Jersey Consumer Fraud Act.

II. STANDARD OF REVIEW

When deciding a motion to dismiss under FED. R. CIV. P. 12(b)(6), all allegations in the complaint must be taken as true and viewed in the light most favorable to the plaintiff. See Warth v. Seldin, 422 U.S. 490, 501 (1975); Trump Hotels & Casino Resorts, Inc., v. Mirage Resorts Inc., 140 F.3d 478, 483 (3d Cir. 1998). In evaluating a Rule 12(b)(6) motion, a court may consider only the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the plaintiff's claims are based upon those documents. Pension Benefit Guar. Corp. V. White Consol. Indus., 998 F.2d 1192, 1196 (3d Cir. 1993). While under the liberal notice pleading standard a plaintiff is not required to plead facts sufficient to prove its case, there still must be an underlying claim for relief before the court. Lum v. Bank of America, 361 F.3d 217, 223 (3d Cir 2004). To defeat a 12(b)(6) motion the plaintiff must provide "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Moreover, "a court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." Morse v. Lower Merion School Dist., 132 F.3d 902, 906 (3d Cir. 1997).

III. DISCUSSION[3]

HOC argues that most of the Counts raised in Mr. Delaney's Complaint must be dismissed because they are preempted by the MDA. HOC further argues that to the extent that some of Mr. Delaney's claims are not preempted, these claims are insufficiently plead and should be dismissed.

A. MDA Preemption

The MDA established a new regime whereby the FDA has almost exclusive authority to regulate medical devices. The MDA requires "various levels of oversight for medical devices, depending on the risks they present." Riegel v. Medtronics,128 S. Ct. 999, 1003 (2008). Under the MDA, medical devices are placed into one of three "classes." Class I devices, such as elastic bandages, pose little or no risk of illness or injury, and are subject only to "general controls" applicable to all devices. 21 U.S.C. § 360c(a)(1)(A). Class II devices, such as wheelchairs, pose potentially greater risks, and their manufacturers must comply with federal performance regulations known as "special controls." 21 U.S.C. § 360c(a)(1)(B). Class III devices, such as the Trident™, "receiv[e] the most federal oversight" because they "'present[] a potential[ly] unreasonable risk of illness or injury'" or are "'for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.'" Riegel, 128 S. Ct. at 1003 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

Of the Class III devices, only a very small subset undergo the "rigorous regime" of the PMA process. See Riegel, 128 S. Ct. at 1004. The vast majority of Class III medical devices are approved through a less rigorous process known as the § 510(k) pre-market notification process. Riegel, 128

[3]Both HOC and Mr. Delaney submitted supplemental authority in support of their arguments. Although the Court reviewed all authority submitted, with the exception of Huber v. Howmedica Osteonics Corp., 2008 U.S. Dist. LEXIS 106479 (D.N.J. Dec. 30, 2008), which the Court was already aware of, none of the supplemental submissions have been relied upon by the Court in formulating the within Opinion.

S. Ct. at 1004 (explaining that in 2005 the FDA approved 3,148 devices through the § 510(k) process, but only 32 devices through the PMA process). Congress devised the PMA process to empower the FDA with the ability to ensure the safety and efficacy of the products that fall within its ambit. As part of the MDA, Congress enacted an express preemption provision to prevent states from imposing additional or different medical device requirements whether directly, or through products liability litigation. 21 U.S.C. § 361k(A); see generally Riegel, 128 S. Ct. at 1003-05; H.R. Rep. No. 94-853, at 12, 45 (1976) (noting the MDA's "general prohibition on non- federal regulation").

The PMA process entails extensive evaluation that is entirely different from the 510(k) pre-market notification process. The FDA retains control of the device even after approval. A manufacturer may not change "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness" without first obtaining the FDA's approval. Riegel, 128 S. Ct. at 1005 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer must receive supplemental PMA from the FDA for any changes, and the FDA evaluates the proposed changes "under largely the same criteria as an initial application." Id. (citing 21U.S.C. § 360e(d)(6)). Even after FDA approval, PMA devices are subject to reporting requirements, including informing the FDA of studies and investigations, or incidents where a PMA device caused or could have caused serious injury. Id. The FDA retains the authority to withdraw approval based on new information. Id.

In Riegel, the Supreme Court established that the small number of Class III medical devices approved pursuant to the FDA's exacting and comprehensive PMA process are exempt from all common law claims that impose requirements that are different from, or in addition to the FDA's

requirements. 128 S. Ct. at 1007, 1011. The Supreme Court in Riegel instructed that the MDA preempts products liability claims, including claims for (1) failure to warn; (2) defective design; (3) negligence and recklessness; and (4) breach of implied warranties including warranties of fitness; and warranties of merchantability. Id. at 1006-7.

The Supreme Court reached its conclusion in Riegel in reliance on the MDA's express preemption provision, which mandates "that no state 'may establish or continue in effect with respect to a device . . . any requirement' relating to safety or effectiveness that is different from, or in addition to, federal requirements." Id. at 1010 (citation omitted). Specifically, the express preemption clause provides:

> [N]o state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement –
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Riegel Court acknowledged that Congress enacted this express preemption provision to prevent states from imposing additional or different medical device requirements, whether directly or through products liability litigation. See 21 U.S.C. §360k(a); see generally Riegel, 128 S. Ct. at 1006, 1010; see also Colacicco v. Apotex Inc., 521 F.3d 253, 261-2 (3d Cir. 2008).

B. The Preempted Claims

Before HOC marketed the Trident™, the device underwent the FDA's comprehensive PMA process. After demonstrating that the device was safe and effective for its intended use, the Trident™ received FDA approval. HOC asserts that each change or modification of the Trident™ has undergone the supplemental PMA process.

Counts One and Three of Plaintiff's Complaint assert claims for failure to warn and defective design. Count Four raises claims of negligence and recklessness. Counts Five, Six and Seven raise claims of implied warranties. Count Seven specifically raises a claim of breach of an implied warranty of fitness. Here, the FDA imposed the same requirements regarding safety and effectiveness as were imposed on the Riegel device. As in Riegel, these claims are expressly preempted because they assert "general tort duties of care," allege that "a device was designed, labeled, or manufactured in an unsafe or ineffective manner," and impose different or additional requirements related to the safety and effectiveness of the Trident™ device. Riegel, 128 S. Ct. at 1010.

Mr. Delaney argues that HOC's assertions in its brief, including that the Trident™ went through the rigorous PMA process and all changes went through the PMA alterations process, are not a matter of public record nor established by indisputable documents and should therefore be ignored. Mr. Delaney further argues that discovery is needed to determine if all or only part of the Trident™ was subject to the PMA process. Discovery is not required in this instance because HOC has sufficiently demonstrated that the Trident™ underwent the PMA process. Moreover, any changes not submitted to FDA for PMA review would constitute a violation of the MDA or rather the FDCA, which the Supreme Court has made clear does not constitute a private right of action. Buckman Co. v. Pl.'s Legal Comm., 121 S.Ct. 1012, 1018 n.4 (2001).

Mr. Delaney argues that before the Court can determine preemption, a choice of law analysis must be performed. Mr. Delaney states that he is a Pennsylvania resident and that his operation took place in Pennsylvania. Despite raising this issue, Mr. Delaney does not undertake a full choice of law analysis in his brief. Nonetheless, the Court agrees that a choice of law analysis would be

needed to determine the New Jersey PLA issues raised by HOC, however, HOC correctly argues that MDA preemption is a federal issue and is unaffected no matter which state law is determined to apply.

Just as in Riegel, Plaintiff's state law claims impose different or additional requirements on a device approved by the FDA under the PMA process, this is expressly prohibited by the MDA. See id. at 1007. Accordingly, these Counts are preempted and are therefore dismissed.

C. The Remaining Claims

Mr. Delaney further argues that there are "a wide array of causes of action against manufacturers of defective medical products that are not preempted." Mr. Delaney provides two examples to support this contention. The first is that defects resulting from manufacturing anomalies are not preempted. Riegel v. Medtronic's, Inc., 451 F.3d 104, 106 (2d Cir. 2006). The second is that state actions that are "parallel" to a Federal legislative scheme may also be brought against defective medical products. The Court recognizes that while the two exceptions discussed by Mr. Delaney do not constitute a "wide array" of non-preempted causes of actions, they do constitute claims that may not be preempted. Mr. Delaney, after suggesting that the meaning of the term "parallel" is unclear, argues that some of his claims are based on violations of Federal law, specifically the FDCA, and are therefore parallel. This argument is based on the Supreme Court's holding in Medtronic v. Lhor. The Lhor Court held that a plaintiff may maintain a cause of action based on claims that the manufacturer violated FDA regulations. 518 U.S. 470, 495 (1996). HOC responds to Mr. Delaney's parallel claims argument with two assertions. First, that the Supreme Court has clearly articulated that there is no private right of action based upon alleged violations of the FDCA. Buckman, 121 S.Ct. at 1018 n.4. Second, that the FDCA violations cited by Plaintiff in his Complaint are not

relevant to his claims and alleged injuries.

Mr. Delaney further argues that MDA preemption does not apply to claims for breach of the Uniform Commercial Code ("UCC") meaning his claims of breach of expressed and implied warranties of fitness, deceptive trade practices, and negligent misrepresentation. Riegel, 128 S.Ct. at 1010.

i. Breach of An Express Warranty

In Count Five of his Compliant, Mr. Delaney in part claims that HOC breached an expressed warranty. Whether New Jersey or Pennsylvania law applies, in order for a plaintiff to establish that there has been a breach of an express warranty, the plaintiff must demonstrate that there was some form of promise or affirmative statement made. Compare N.J.S.A. § 12A:2-313 with 13 Pa. C.S. § 2313. Mr. Delaney's Complaint does not sufficiently allege that any promise, either verbal or written was made by HOC. The Complaint does not establish how or by whom a promise was made nor what exactly was promised. As the Supreme Court explained in Bell Atlantic v. Twombly, "a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level." 127 S.Ct. 955, 1964-65.

HOC contends that Mr. Delaney's claim could only be based on product labeling. HOC argues that any claims arising from product labeling are preempted because the Trident™ product labeling and any subsequent changes were approved through the PMA process. See Adkins v. Cytyc Corp., 2008 WL 2680474, at *2 (W.D. Va. Jul. 3, 2008).

Riegel did not specifically address preemption with regard to a claim for breach of an express

warranty. 128 S. Ct. at 1006 n.2. In Riegel, at the district court level, the Court found that the MDA did not preempt a breach of express warranty claim but later granted summary judgment to Medtronic on that claim for other reasons. Id. Without addressing the issue of preemption, the Third Circuit affirmed the grant of summary judgment. As a result, preemption of express warranty claims based on product packaging was not and has not been considered by the Supreme Court. Id. As discussed in Huber v. Howmedica Osteonics Corp., the absence of Supreme Court guidance means that the Michael v. Shiley opinion controls. 2008 U.S. Dist. LEXIS 106479, at *10 (D.N.J. Dec. 30, 2008) (referring to Michael v. Shiley, 46 F.3d 1316 (3d Cir. 1995) (overruled on other grounds)).

In Shiley, the Third Circuit held that the MDA did not preempt a breach of express warranty claim based on statements found on product packaging. 46 F.3d at 1325. The Shiley Court found that express warranties arise from a contractual commitment and not from the independent operation of state law. Id. "The fact that the FDA approves the label does not undermine 'the doctrine that contractual duties arise from the mutual assent of parties to agreed upon language.'" Huber, 2008 U.S. Dist. LEXIS 106479, at *8 (citing Shiley, 46 F.3d at 1327). The Shiley Court further found that the enforcement of an express warranty arising "from FDA approved packaging does not establish a requirement that is different from, or in addition to, a federally imposed requirement." Id. The Shiley Court justifies its holding regarding express warranties by explaining that express warranty claims allow plaintiffs to enforce the very language which the FDA approved. Id. In accordance with Shiley, this Court must conclude that express warranty claims based on FDA approved product packaging are not preempted by the MDA.

Nonetheless, the Court agrees with HOC that Mr. Delaney has insufficiently plead his express warranty claim. In Shiley, the plaintiff clearly plead what affirmative statement he was relying on

to substantiate his express warranty claim. See 46 F.3d at 1326. Indeed the Shiley Court at several places provided at length the affirmative statement the defendants made. "Shiley represented: Shiley warrants that reasonable care has been used in the manufacture of this device." Id. Mr. Delaney has not alleged any facts to demonstrate that HOC made an express warranty. Above, the Court noted that HOC assumes that Mr. Delaney's express warranty claim is based on product packaging but Mr. Delaney did not specify this in his Complaint. Mr. Delaney failed to provide the grounds upon which his breach of express warranty claim is based. Although Mr. Delaney is only required to provide a short and plain statement of his claims, he must provide more than labels and conclusions. See Papasan v. Allain, 478 U.S. 265, 286, 106 S. Ct. 2932, 92 L. Ed. 2d 209 (1986); See Bell Atl. Corp. v. Twombly, 127 S.Ct. 1955, 1966 (2007). Given the concerns outlined above, the Court will **grant** Mr. Delaney leave to amend his Complaint as to his express warranty claim only.

ii. Manufacturing Defect

Count Two of Mr. Delaney's Complaint raises a manufacturing defect claim. Specifically, the Complaint asserts that an "impurity, imperfection, and/or another product defect" occurred. To maintain a manufacturing defect cause of action in New Jersey, "a plaintiff must prove that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, [who must be] a reasonably foreseeable or intended user." Myrlak v. Port Authority of N.Y. and N.J. *et.al*, 157 N.J. 84, 97 (1999). To establish proximate causation, a plaintiff must show that the "product constituted a 'substantial factor' in bringing about" the injury alleged. Reiff v. Convergent Techs., 957 F. Supp. 573, 578 (D.N.J. 1997).

The Complaint does not specify in what way HOC deviated from the manufacturing process

that the FDA approved. No facts have been asserted to support the bald allegation that the Trident™ fractured because of a manufacturing defect. The Complaint does not allege that the Trident™ implanted in Mr. Delaney left HOC's custody in a defective condition. Mr. Delaney cannot avoid Riegel preemption simply by labeling a product defect claim a "manufacturing defect" claim. In order to properly allege a manufacturing defect claim, Mr. Delaney must allege that "'something was wrong' with the product. The mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." Myrlak, 157 N.J. at 98 (citation omitted).

Likewise, Mr. Delaney's cause of action for strict liability manufacturing defect cannot survive under Pennsylvania law. Pennsylvania law mirrors New Jersey law in that under Pennsylvania law, to substantiate a product defect claim the plaintiff must demonstrate that the product was defective, that the alleged defect existed when the product left the manufactures control, and that the alleged defect proximately caused the plaintiff's injury. Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 749 (E.D. Pa. 2007). Additionally, Pennsylvania has adopted Section 402A of the Restatement (Second) of Torts, which imposes strict liability on manufacturers of products sold "in a defective condition unreasonably dangerous to the user or consumer." Mazur v. Merck & Co., 964 F.2d 1348, 1353 (3d Cir. 1992). This notwithstanding, Mr. Delaney cannot maintain a strict liability manufacturing defect claim against a manufacturer of a medical device under Pennsylvania law. Comment k of Section 402A denies application of strict liability to products considered "unavoidably unsafe," such as prescription drugs. Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996). This prohibition has been extended to medical devices. See Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006).

As Mr. Delaney has not pointed to a defect or a deviation from the FDA-reviewed Trident™

manufacturing specifications regarding the Trident™ implanted in him, the Court dismisses Mr. Delaney's manufacturing defect claim.

iii. Consumer Fraud

In Count Eight of his Complaint, Mr. Delaney argues that HOC violated New Jersey consumer fraud law. Mr. Delaney argues that a choice of law analysis is required to see whether New Jersey or Pennsylvania law applies to his other claims, but for some reason thinks that he is able to elect to the application of New Jersey law to his consumer fraud claim. Without addressing the obvious choice of law issues this presents, the Court will apply New Jersey law to Mr. Delaney's consumer fraud claim for the purposes of this motion.

The New Jersey Products Liability Act ("PLA") requires that Mr. Delaney's consumer fraud claim be subsumed by the PLA and cannot be brought as a separate cause of action. N.J.S.A. § 2A:58C *et seq.* The PLA provides the sole method of prosecuting a New Jersey consumer fraud claim when the claim is based on harm caused by a product. Tirrell v. Navistar, 248 N.J. Super. 390, 398-99 (App. Div. 1991), cert. denied, 126 N.J. 390 (1991). Pursuant to the PLA, any claim that falls within its scope, as consumer fraud does, is subsumed by it, and a strict liability claim is the only surviving cause of action. Id. at 399 n.5. This has been reaffirmed by the New Jersey Supreme Court in Sinclair v. Merck & Co., Inc., 948 A.2d 587, 589, 595-96 (N.J. 2008). The New Jersey Supreme Court explained that "'[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products.'" Id. at 595 (citation omitted). The Third Circuit has similarly held that product-based claims are subsumed by the PLA and therefore must be dismissed. Repola v. Morbark Indus., Inc., 934 F.2d 483, 492 (3d Cir. 1991).

Mr. Delaney's claim of consumer fraud is a product liability action within the ambit of the PLA. It is therefore subsumed by the PLA leaving only a strict liability claim that is preempted by the MDA.

IV. CONCLUSION

Based on the foregoing, Defendants' motion to dismiss Mr. Delaney's Complaint pursuant to FED. R. CIV. P. 12(b)(6) is **granted** in part and **denied** in part. Mr. Delaney shall have thirty (30) days from the issuance of this Opinion and the corresponding Order to amend his Complaint regarding his express warranty claim. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: March 5, 2009
Orig.: Clerk
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
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